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No. 80-2067

In the Supreme Court of the United States

October Term, 1980

JERRY J. COLAHAN, *et al.*,
Petitioners,

vs.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI
To the United States Court of Appeals
For the Sixth Circuit

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QUESTIONS PRESENTED

1. Does the proviso of Section 502(f) of the Food, Drug & Cosmetic Act, 21 U.S.C. §352(f), ("§502(f)"), authorizing the Secretary of Health and Human Services to promulgate regulations exempting certain drugs from the statutory requirement of "adequate directions for use" only when adequate directions for use are "not necessary for the protection of the public health", impliedly authorize the Food and Drug Administration to require that animal drugs designated by it be sold only under a veterinarian's prescription and meet other certain mandatory conditions? The District Court said it did not; the Court of Appeals for the Sixth Circuit said it did.

2. Does Section 502(f) authorize the Secretary of Health and Education to define, by regulation, "prescription drug" to include "veterinary drug"? The District Court said it did not; the Court of Appeals for the Sixth Circuit said it did.

3. Does §502(f) prevent a person charged with "misbranding" under that section for selling animal drugs that bear a prescription legend from presenting, as a complete defense, that those drugs bore "adequate directions for use"? The District Court has not yet reached this issue; the Court of Appeals for the Sixth Circuit said it did not.

LIST OF ALL PARTIES

Parties Petitioner:

Jerry J. Colahan
Norman F. Bauer
Robert L. Berkshire
John D. Burrows
Russell C. Humphrey, Jr.
Simon E. Miller
Ralph A. Scharver

Parties Respondent:

United States of America

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vs.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI
To the United States Court of Appeals
For the Sixth Circuit

The Petitioners, Jerry J. Colahan, *et al.*, respectfully ask that a Writ of Certiorari issue to review the final opinion of the United States Court of Appeals for the Sixth Circuit entered in this proceeding on December 11, 1980. Rehearing was denied on March 5, 1981, which action overruled and denied Petitioners' Petition for Rehearing or in the Alternative Rehearing En Banc of the Court's decision entered December 11, 1980.

OPINIONS BELOW

The opinion of the Court of Appeals for the Sixth Circuit is reported at 635 F.2d 564; the District Court for the Northern District of Ohio's opinions are unreported. All opinions appear in the Appendix hereto.

JURISDICTION

The opinion of the Court of Appeals for the Sixth Circuit was entered on December 11, 1980. A timely Petition for Rehearing or, in the Alternative, Rehearing En Banc was denied on March 5, 1981, and this petition was filed within 90 days of that date. The jurisdiction of this Court is invoked under 28 U.S.C. §1254 (1).

STATUTORY PROVISIONS INVOLVED

United States Code, Title 21:

§352 (f)—

A drug or device shall be deemed to be misbranded —

. . . .

> (f) Unless its labeling bears (1) adequate directions for use . . . provided, that where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

Code of Federal Regulations, Title 21:

§201.105 *Veterinary drugs.*

A drug intended for veterinary use which, because of toxicity or other potentiality for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The drug is:

(1) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of veterinary drugs and is to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice; or

(2) In the possession of a licensed veterinarian for use in the course of his professional practice.

(b) The label of the drug bears:

(1) The statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; and

(2) The recommended or usual dosage; and

(3) The route of administration, if it is not for oral use; and

(4) The quantity or proportion of each active ingredient as well as the information required by section 502(e) of the act; and

(5) If it is for other than oral use, the names of all inactive ingredients, except that:

(i) Flavorings and perfumes may be designated as such without naming their components.

(ii) Color additives may be designated as coloring without naming specific color components unless the naming of such components is required by a color additive regulation prescribed in Subchapter A of this chapter.

(iii) Trace amounts of harmless substances added solely for individual product identification need not be named.

If it is intended for administration by parenteral injection, the quantity or proportion of all inactive ingredients, except that ingredients added to adjust the pH or to make the drug isotonic may be declared by name and a statement of their effect; and if the vehicle is water for injection, it need not be named.

(6) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug;

Provided, however, That in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, but which are packaged within an outer container from which they are removed for dispensing or use, the information required by paragraphs (b)(2)(3), and (5) of this section may be contained in other labeling on or within the package from which it is to be so dispensed, and the information referred to in paragraph (b)(1) of this section may be placed on the crimp of the dispensing tube.

STATEMENT OF THE CASE

This petition arises from a complaint brought by the Food and Drug Administration ("FDA") alleging that the petitioners (also referred to as "Colahan") received and sold animal drugs that were misbranded under §502(f)(1) of the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §352(f)(1) ["§502(f)"]. Section 502(f)(1) deems a drug "misbranded", unless its labeling bears "adequate directions for use".

Pursuant to this section, the FDA promulgated regulation 21 C.F.R. §201.105 ("201.105"), which, *on its face* relieves an animal drug from the requirement of §502(f)(1) for "adequate directions for use" if the label bears a "prescription legend": "Caution: Federal law restricts this drug to sale by or on order of a licensed veterinarian." The *effect* of the regulation however is that:

1. the definition of "prescription drugs" now includes "veterinary drugs" by regulatory fiat rather than by legislative determination.

2. a manufacturer may insure marketing of its drugs only through veterinarians simply by adding the "restriction label" to the animal drug.

3. petitioners cannot overcome a charge of misbranding under §502(f) by establishing, through credible expert evidence, that the directions on the label constitute "adequate directions for use" if the drug bears a "restriction legend".

None of these results are authorized by §502(f).[1]

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1. §502(f), which deems a drug misbranded unless its labeling bears adequate directions for use, authorized the issuance of exempting regulations *only* where such labeling directions are "not necessary for the protection of the public health." Exempting regulations were issued for human "prescription drugs" 21 C.F.R. 201.100. The heading of §201.100 is *"Prescription Drugs for Human Use"*, and the regulation explicitly states that "A drug subject to the requirements of Section 503(b)(1) of the Act shall be exempt from Section 502(f)(1) if all of the following conditions are met: * * *" Only *human* drugs subject to Section 503(b)(1) are referred to. §201.105 is headed simply: *"Veterinary Drugs"* and the initial paragraph makes no reference to its statutory authority for designating "veterinary drug" to be included under "prescription drugs." Thus the separate sections for "prescription drugs" dealing with humans and "veterinary drugs" dealing with animals are a recognition of the Congressional distinction. Section 502(N), added by the Drug Amendments of 1962, deems a "prescription drug" to be misbranded unless it complies with the requirements set forth therein for "prescription

(Continued on following page)

The District Court and petitioners contend that no simple change in regulatory language can properly define "prescription drug" to include "veterinary drug", since the sole statutory basis for the definition of "prescription drugs" clearly limits it to drugs for use by man, and the sole authority for §201.105 is §502(f), which deals only with *labeling* [see footnote 1, *supra*]. The FDA charged these petitioners with misbranding of certain animal drugs, even though the labels on each of said drugs bears "adequate directions for use" simply because of the presence of the manufacturer's caution legend. The FDA contends, and the Court of Appeals agreed, such legend on the label forecloses petitioners from establishing that said animal drugs are not misbranded by demonstrating that each bears adequate directions for use, pursuant to §201.105.

A. Proceedings in the Trial Court

Upon filing the Complaint, the FDA obtained an *ex parte* temporary restraining order ("TRO"). On November 9, 1978, the parties entered into a stipulated order "in lieu of extending the Temporary Restraining Order" and the *ex parte* TRO expired.[2]

The FDA, in the District Court, claimed that the animal drugs were misbranded under §502(f), pursuant to §201.105,

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Footnote continued—

drug" advertisements. The FDCA on June 27, 1968 defined prescription drug to include drugs defined in section 503(b)(1) of the Act which *dealt with human drugs only*. Section 201.105 was issued pursuant to §502(f), which deals only with *labeling* and *not* "prescription drugs" as did 503(b)(1). Kushen, *FDA: A Case Study In Administrative "Legislation"*, 24 THE BUSINESS LAWYER 261, 265-266, 1968.

2. The stipulated order was specifically stated to be "in lieu of continuation of the Temporary Restraining Order" and provided that it would remain in effect "until further order of this Court [District Court]". It thus was, by its terms, subject to being vacated by the District Court, which is what happened upon motion of petitioner.

solely because the labels bore the cautionary veterinarian legend but did not contend, in the District Court, that said drugs could not bear adequate directions for use.[3]

On October 9, 1979, following extensive briefs and oral hearings, the District Court vacated, on the Motion of Petitioners, the stipulated order, as provided by the terms of the order itself, while ordering the case advanced for hearing on the merits of the FDA's requested preliminary and permanent injunctive relief. The District Court denied only the FDA's motion to certify its October 9, 1979, order as an interlocutory order pursuant to 28 U.S.C. §1292(b) on the ground that it had not issued a final order in vacating the stipulated order in accordance with its terms which specifically permitted the District Court's action. The District Court *never* denied or issued an order denying FDA's Motion for Preliminary Injunction.[4]

B. Proceedings in the Court of Appeals

The Court of Appeals for the Sixth Circuit reversed the District Court in an opinion filed December 11, 1980. The timely request of petitioners for a rehearing or, in the alternative, rehearing *en banc*, was denied on March 5, 1981.

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3. As will be noted the Court of Appeals accepted FDA "new" argument, contrary to its position in the District Court, that if an animal drug bears the cautionary legend then it is impossible to have "adequate directions for use". *The Circuit Court's decision fails to explain what federal law so states as to animal drugs*—there simply is none.

4. The District Court ordered the FDA's Motion for Preliminary and Permanent Injunction advanced to a hearing on the merits. The FDA, instead of proceeding to a hearing on the merits, filed a motion to stay all proceedings and filed a notice of appeal from the Order of October 9, 1979, to the United States Court of Appeals for the Sixth Circuit.

The FDA, in its appeal, requested relief that was not even properly before the Court of Appeals.[5] The Court of Appeals also denied petitioners' motion to dismiss the appeal pursuant to Rule 8(a), Rules of the Court of Appeals for the Sixth Circuit, on the grounds there was no interlocutory order by the District Court "granting, continuing, modifying or dissolving injunctions" pursuant to 28 U.S.C. §1292(a)(1).[6]

The Court of Appeals, in reversing the District Court, unilaterally changed the terms of the stipulated order, previously agreed to by the parties with the consent of the District Court and, in effect, granted the FDA's request for preliminary and permanent injunction against petitioners without affording petitioners an opportunity for a hearing on the merits of said requested injunctive relief and effectively foreclosing petitioners from establishing said drug bore "adequate directions for use" so as not to be considered misbranded under §502(f).

C. Animal Drugs vs. Human Drugs

The Court of Appeals accepted the unsupported assertion by the FDA that the "plain meaning" interpretation

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5. "Because the October, 1979 Order vacating the stipulated injunction, *granting Colahan's motion for a preliminary injunction and denying the government's motion for an injunction* was based on clear legal error, it should be reversed. * * * For the reasons stated, the order of the district court should be reversed and *the injunction vacated.*" (U.S. Brief, p. 32, before the Court of Appeals—italicized portion represents issues not appealed).

6. The District Court did not deny or dissolve any motion for preliminary injunction. There was *no* injunction granted, dissolved or denied. To the contrary, the District Court ordered FDA's motion for preliminary and permanent injunction advanced for hearing. The FDA, instead of proceeding to a hearing on the merits, filed a motion to stay all proceedings and filed a notice of appeal from the Order of October 9, 1979, to the United States Court of Appeals for the Sixth Circuit.

of §502(f)(1) would allow unrestricted over-the-counter sale of *all* veterinary drugs and require withdrawal of useful animal drugs from the market that FDA considers dangerous unless sold by prescription. There was absolutely no evidence in the record before the Court of Appeals to support such an assertion, and it simply is not accurate.

The record below, however, did establish that all or some of these restricted animal drugs are available as unrestricted over-the-counter drugs under different names.[7] There is no evidence that these drugs fail to bear adequate directions for use.[8] The FDA has more than adequate statutory authority, other than §201.105, to protect against misuse of dangerous animal drugs, including authority to protect against (1) drug residues in animals raised for human consumption and (2) misuse of animal drugs by humans.

D. FDA "Long-Standing" Interpretation

The Court of Appeals indicated it was persuaded by the FDA's "long-standing exercise of authority to issue and

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7. Petitioners contend that the animal drugs are not misbranded since the labeling of each bears directions adequate for the intended use. The fact that a veterinarian caution legend is indiscriminately placed upon the label by the manufacturer, for reasons other than safety and unrelated to public health, such as marketing and distribution policy, does not render a layman incapable of following adequate label instructions to direct him in the intended use of the animal drug. The Court of Appeals decision would foreclose such evidence.

8. One of the questions and answers in the 1951 House hearings on H.R. 3598, August 1, 1951, the Durham-Humphrey Bill, was as follows, at 9323:

> *Twenty-Ninth Question*: Why should some manufacturers desire to restrict drugs to sale on prescription only, although they would safely be sold over the counter without a prescription?
>
> *Answer*: Several drug manufacturers have traditionally in their trade catered to physicians and registered pharmacists. Many physicians prefer to buy or promote medicines of firms who sell their drugs this way.

enforce §201.105" and that the administrative interpretation over many years was entitled to great weight. The decision misconstrues the FDA's "long-standing" interpretation prior to petitioners' challenge. The Court of Appeals must not accept as "interpretation" that which is nothing more than the current FDA's "belief" as to what is best for the public—a belief held despite *contrary expressions by Congress and its own agency.* The Court of Appeals totally ignored the continuing congressional emphasis on the recognized *distinction between human and animal drugs* —specific congressional authority was granted *for exempting prescription human* drugs by enactment of §503(b)(1)(B)—no similar statutory authority was granted as to animal drugs. Under these circumstances it is clear that the Court of Appeals' opinion was not warranted by the principle requiring due regard be given to administrative interpretation. *Becton, Dickinson & Co. v. Food and Drug Administration,* 589 F.2d 1175, 1181 (2d Cir. 1978).

The conclusion of the Court of Appeals that its decision was based upon a "long-standing agency interpretation" is and was contrary to the record before that Court. As recently as 1974-79, when the complaint was filed, the FDA's official position was this:

> *"The Congress specifically omitted animal drugs from prescription legend requirements on the basis that a man's animals are his private property and he may diagnose and treat their ailments as he sees fit.* This means that in any case where adequate directions for lay use may be written, the animal drug must be freely marketed. . ." (Emphasis supplied). Bureau of Veterinary Medicine, HEW Pub. No. (FDA) 74-6012, Rvd. May, 1978.[9]

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9. *After* the District Court's Order, the FDA *amended* said release to conform to its "new" interpretation.

This was the official FDA interpretation prior to the instant action.

In 1953, another spokesman for the FDA stated the official interpretation as follows:

> *"Officially,* we must take the position that every owner of animals has the unalienable human right to make his own diagnosis and to attempt treatment of his own animals, which admittedly are his property...
>
> ". . . We must recognize that *Congress* sets policy when it enacts laws, and, in this instance, *the medication of animals by their owners has been accepted as public policy. . .*" (Emphasis supplied). Collins, *Federal Drug Regulations As They Apply To Veterinarians,* 8 FOOD DRUG COSMETIC JOURNAL, 333, 335 (May, 1953).

Again, in 1957, the former chief of the Philadelphia district of FDA stated the "long-standing interpretation" of the FDA as follows:

> "Under the Act *according to the Food & Drug Administration's interpretation,* the owners of animals have the right to attempt to make their own diagnosis and to attempt treatment of their own animals. . ." (Emphasis added). Stanfill, Chief of Philadelphia District of FDA, *Facts About The Food & Drug Administration,* Pennsylvania Veterinary Medical Association, Lancaster, Pennsylvania, October, 1957.

Even prior to 1951, the FDA admitted that it was questionable that they had any authority to differentiate between "prescription drugs" and "over-the-counter drugs" or to forbid the sale of prescription drugs without a prescription. It was for this very reason that the FDA

sought clear and unequivocal congressional authority to prohibit the sale of prescription drugs without a prescription. However, Congress gave that authority to the FDA only in the case of human drugs. Durham-Humphrey Amendments, 65 Stat. 648 (1951). This new amendment to the FDCA specifically allowed the FDA to require prescription sales *only* when the drug is:

> A drug intended for use by *man* which—* * *
>
> (b) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; * * * [21 U.S.C. §353(b)(1).] (Emphasis added).

Alan Kushen commented on the amendments in this way:

> "The Durham-Humphrey Amendment has been in effect since 1952 and, as we all know, requires that certain drugs be dispensed only on written prescription of a licensed practitioner. We are all equally familiar with the statutory legend 'Caution: Federal law prohibits dispensing without prescription.' *One might not always remember, however, that all of Section 503(b) reads on drugs 'intended for use by man'* (Emphasis supplied). *The legislative history of the Durham-Humphrey Amendment amply supports the position that it was clearly not meant to apply to veterinary drugs."* Kushen, *FDA: A Case Study In Administrative "Legislation"*, 24 THE BUSINESS LAWYER 261 (1968) (Emphasis added).

This same article addressed the FDA's "promulgation" of regulation §201.105 [then codified as §1.106(c)] which is the regulation purportedly issued under authority of the

proviso to §502(f)(1). The author observed that the promulgation of this regulation constituted but another "classic example of [the FDA] pulling one's self up by one's own bootstrap". The manner in which the FDA accomplished this was as follows:

> ". . . FDA inserted into §1.106(c) [now §201.105] as one of the conditions of the exemption for 'veterinary drug,' that the label bear the legend 'Caution: Federal Law restricts this drug to sale by or on order of a licensed veterinarian.' *What federal law so restricts?*
>
> *"It [the FDA] overlooks completely the fact that §1.106(c) [now §§201.105] was issued pursuant to §502(f), which deals only with labeling.* No simple change in regulatory language can properly define 'prescription drug' to include 'veterinary drug' since the sole statutory basis for the definition clearly limits it to drugs for use by man." *Id.* at 264. (Emphasis added).

The FDA's interpretation is further reflected by its introduction, in 1980, before the 96th Congress, of H.R. 7035 to amend the FDCA. This 1980 Bill, which was not passed out of committee, stated in the amendment which *would* if adopted authorize a regulation similar in part to §201.105:

> "Section 104 of the Bill *would* provide exclusively for the category of animal drugs which *may* be dispensed only under a veterinarian prescription."

Thus, this 1980 Bill would have amended §503 to provide the *statutory* authority the FDA now lacks to regulate animal prescription drugs in the same manner as the Durham-Humphrey Amendments in 1951 authorized reg-

ulation of *human* prescription drugs (§503(b)(1), 21 U.S.C. §353 (b)(1)). The Court of Appeals decision totally ignored all the legislative and agency acknowledgments of the difference between human and animal drugs. *Each* of the drug cases relied upon by the Court of Appeals dealt solely with *human drugs* and not animal drugs.[10]

Every known article or text published on the subject has recognized this distinction, in statutory regulation, between animal drugs [veterinary drugs] and human drugs [drugs intended for use by man], a controlling distinction which the decision of the Court of Appeals failed completely to recognize.

> "There is a different philosophy for drugs designated for veterinary use. *The owners of animals have the right to diagnose the ailments of their pets or livestock and to treat them by injection, internal medication or otherwise,* and directions for use must be adequate for lay use except in a comparatively few examples of highly potent drugs. If an owner miscalculates, human life is not endangered. Injury or death of an animal is an economic loss which is different from injury or death of a human being." (Emphasis supplied) 3 TOULMIN, LAW OF FOOD & DRUG COSMETICS, Chapter 47, p. 1069.

This distinction between human and animal drugs has continually been espoused by Congress. (Cong. Rec. No. 6, 1967, Animal Drug Amendments H.R. 3639, Page 31292.) It had been the "long standing interpretation" of the FDA until the instant case.

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10. *United States v. El-O-Pathic Pharmacy*, 192 F.2d 62 (9th Cir. 1951), *United States v. Articles of Drug . . . Mykocert*, 625 F.2d 665 (5th Cir. 1980). *El-O-Pathic, supra*, erroneously concluded that 502(f) required a prescription legend for human drugs.

REASONS FOR GRANTING THE WRIT

1. The decision of the Court of Appeals for the Sixth Circuit conflicts in principle with the decision of this Court in *United States v. Sullivan*, 332 U.S. 689 (1948), where Justice Rutledge, in his concurring opinion, concluded that the plain meaning of the four-line proviso of §502(f) conformed to that of the district court rather than that of the Court of Appeals.[11] The important question of federal law as to animal drugs decided by the Court of Appeals in this case, has not been previously addressed or settled by this Court.

2. The Court of Appeals erred in concluding that an animal drug bearing veterinarian caution legend could not also bear "adequate directions for use" under §502(f) so as not to be misbranded.

3. The decision of the Court of Appeals conflicts with decisions of this Court and other Courts of Appeals on the Final Judgment Rule since the vacating of a stipulated order and advancing a request for injunctive relief to a hearing on the merits was not the equivalent of dissolving or refusing an injunction on the merits.

4. The decision of the Court of Appeals in effect granted FDA's motion for preliminary and permanent injunctive relief without affording petitioners a hearing on the merits.

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11. The Court of Appeals has granted the FDA authority to regulate animal drugs, as distinguished from human drugs, by prescription legend where Congress expressly refused to do so, where there is no clear legislative history supporting such extention, where the Agency's prior interpretations did not authorize such extension, and where such an extension is not necessary to effectuate the purpose of the Food, Drug & Cosmetic Act.

1. The Decision of the Court of Appeals for the Sixth Circuit Conflicts in Principle With the Decision of This Court in United States v. Sullivan, 332 U.S. 689 (1948), Where Judge Rutledge, in His Concurring Opinion, Concluded That the Plain Meaning of the Four-Line Proviso of §502(f) Conformed to That of the District Court and Not the Court of Appeals.

United States v. Sullivan, supra, concerned a retail druggist who received a number of bottles of a *human* drug called sulfathiazole. The bottles had a prescription label. On two separate occasions twelve tablets were removed from the labeled bottles, put in unlabeled pill boxes, and sold to customers.

The issue in *Sullivan* was whether the Act's requirement that it be applied only to persons who performed acts resulting in drug misbranding while the drug was "held for sale after shipment in interstate commerce" exempted the local retailer. This Court held it did not.

The question of the authority for requiring prescription sale could have been raised by the facts of *Sullivan,* but was neither briefed nor dealt with in the Court's opinion. The question was, thus, never brought before this Court.[12]

However, the Court did have occasion to consider the general nature of the FDCA. Justice Rutledge, in his concurring opinion, noted that:

"The Act is long and complicated. Its numerous provisions treat the very different subjects of drugs, food

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12. The decision of the Court of Appeals erred in allowing the FDA to include animal drugs in prescription legend requirements by regulation when "Congress specifically omitted animal drugs from prescription legend requirements on the basis that a man's animals are his private property and he may diagnose and treat their ailments as he sees fit." (See text, *supra,* preceding footnote 10.)

> and cosmetics alike in some respects, differently in others. *The differences are as important as the similarities, and cannot be ignored." United States v. Sullivan, supra* (emphasis added), at p. 699.

Of course, *Sullivan* was decided before the 1951 Durham-Humphrey Amendments; it was, in fact, one of the primary reasons for the adoption of the Amendments as to human drugs. Justice Rutledge was therefore speaking of both human and animal drugs when he interpreted the "proviso" language of §502(f)(1) now relied upon by FDA as authority for promulgating §201.105. Justice Rutledge's interpretation of the plain meaning of those words is important:

> "The intent to protect the public health is further emphasized by the limited scope of the proviso, which directs the Administrator to make exemptions only when clause (1) 'is not necessary for the protection of the public health.' " (at p. 702.)

Justice Rutledge's views were echoed by the majority at pages 694-695 and by the Trial court in the instant case in applying this same plain meaning to the same words. The Court of Appeals ignored the *Sullivan* decision in its opinion.

The FDCA covers a broad range of items—food, cosmetics, human drugs, animal drugs, medicinal devices, and the like. *Sullivan* emphasized that the statutory differences in the way these diverse items are handled must be given close scrutiny and full effect for the proper and fair administration of the statute. The Court of Appeals' interpretation of Section 502(f) and regulation §201.105 is in direct contradiction to the Court's guidelines set out in *Sullivan*. The decision in *Sullivan* did not allow the unrestricted over-the-counter sale of all human drugs or

devices nor would it as to veterinary drugs. FDA has sufficient authority without §201.105 to protect the public from so-called potent or dangerous animal drugs. Further, FDA can and has in the past sought congressional authority to designate animal drugs as "prescription drugs", but *such authority has not been given.*[13]

The legislative history of §502(f) establishes that no implicit exemption for animal drugs bearing a prescription legend "is necessary to attain congressional objectives or to avert an unreasonable reading" of the proviso to §502(f)(1), "not necessary for the protection of the public health". *Id.* at p. 2475.[14]

The District Court's Order of October 9, 1979, emphasized that any possible presumption as to the validity of administrative regulations is "annulled and found unenforceable when in excess of statutory authority as determined by the natural and plain meaning of the congressional enactment". The District Court correctly concluded that "the proviso to §352(f)(1) [§502(f)(1)] speaks plainly and unequivocally".

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13. See H.R. 7035, 96th Cong. 20 Session April 2, 1980 (Section 104), which would provide for a category of prescription animal drugs, which does not presently exist. The Bill was not adopted.

14. In the Congressional hearings on the 1938 Federal Food, Drug and Cosmetic Act the committee analyzed the misbranding provision of the act on drugs and devices, Section 502(f) which was amended to its present form. The report clearly states that Section 502(f) is a labeling statute and permits the Secretary by regulation to prescribe "warnings". It was not intended to restrict availability of drugs for self-medication. Other provisions of Section 502 are designed to require the labeling of drugs and devices with information essential to the consumer. The bill is not intended to restrict in any way the availability of drugs for self-medication. On the contrary, it is intended to make self-medication safer and more effective. For this purpose provisions are included in this section requiring the appropriate labeling of habit-forming drugs, requiring that labels bear adequate directions for use and warnings against probable misuse, and setting up appropriate provisions for deteriorating drugs.

As the Second Circuit stated in rejecting the government's construction of another provision of the Act in *Toilet Goods Association v. Finch*, 419 F.2d 21 (2d Cir. 1969):

> ". . . the language is too clear for us to read it as meaning something different from what it so plainly says, at least in the absence of *persuasive* legislative history. The case fits perfectly Mr. Justice Brandeis' famous stricture, *'what the Government asks is not a construction of the statute, but, in effect, an enlargement of it by the court,* so that what was omitted, presumably by inadvertence, may be included within its scope.' " (Emphasis supplied). 419 F.2d at 29.

In the *Toilet Goods* case, in construing FDA regulatory power, the District Court reasoned:

> ". . . if Congress had intended to confer upon the FDA the regulatory powers which that agency has assumed in the Regulations * * *, it could have easily done so in simple and unambiguous language. Congress did not do so, and the obvious implications from the negative are fortified by the legislative history of the 1960 Amendments.
>
> * * * *the point of this case is that Congress, and not the FDA or the Federal Courts, has the power to establish * * * consumer protection.*" (Emphasis added). *Toilet Goods Association v. Gardner*, 278 F. Supp. 786, 793-4 (S.D.N.Y. 1968) *aff'd in part in Toilet Goods Association v. Finch*, 419 F.2d 21 (2d Cir. 1969).

This Court has further held that agency interpretations which rest on an erroneous legal foundation, or which are inconsistent with a statutory mandate, must be struck down. *NLRB v. Brown*, 380 U.S. 278, 85 S. Ct. 980 (1965); *Federal Maritime Commission v. Seatrain Lines, Inc.*, 411

U.S. 726, 93 S. Ct. 1773 (1973), and that an administrative construction of an act which is clearly erroneous is not persuasive in judicial proceedings. *Florida Citrus Exchange v. Folsom*, 246 F.2d 850 (5th Cir. 1957), *rev'd on other grounds*, 385 U.S. 153, 79 S. Ct. 160 (1958), *reh. den.* 79 S. Ct. 349.

The principle that an agency's construction of its own regulations is entitled to great weight normally applies *only* where the relevant statutory language is unclear or is susceptible of differing interpretations. *Shea v. Vialpando*, 416 U.S. 251, 94 S. Ct. 1746 (1974). In construing what Congress has written in the proviso to 502(f)(1), neither the FDA nor this Court can add, subtract, delete or distort the words used therein. *62 Cases etc. v. United States*, 340 U.S. 593 (1951); *See also, United States v. Goldenberg*, 168 U.S. 95, 103 (1897), cited by the District Court in its opinion and order.

The District Court in this case concluded, as did this Court in *United States v. Sullivan, supra*, 332 U.S. 702-703, that the statutory proviso to §502(f)(1) is not ambiguous and calls for a common sense and literal reading. The requisite congressional intent for the FDA to have promulgated §201.105 on the authority of the proviso to §502(f)(1) is clearly not present. Simply stated, the Court of Appeals failed to give effect to the plain meaning of the statutory proviso of §502(f)(1) despite this Court's admonition in *Sullivan* to the contrary.

2. The Court of Appeals Erred in Concluding That an Animal Drug Bearing a Veterinarian Caution Legend Could Not Also Bear "Adequate Directions for Use" Under §502(f) So As Not to Be Misbranded.

After deciding that the District Court's action, which granted a motion to vacate the stipulated order, was appeal-

able and that the District Court's order was in error, the Circuit Court went on to decide an issue which the District Court has not yet reached. That issue is whether by the mere affixation to a label of an animal drug of a warning "Caution: Federal Law restricts this drug to use by or on the order of a licensed veterinarian" it is *per se* impossible for "adequate directions for use" to be written as required by §502(f).

In order to satisfy the basic statutory mandate of §502(f)(1), all drugs, whether human or animal, had to bear information for all conditions for which the drug was intended to be prescribed, recommended, or suggested in its labeling and all had to bear information on dosage, frequency of use, duration of use, time of use, root of use and preparation for use. This is the very type of information, translated to veterinarian use, these nine drugs contain, in addition to other information, in their labeling. There has been no testimony or evidence to the effect that said labels do not contain "adequate directions for use".

The so-called "lay use" requirement for adequate directions was not utilized until 1952 *after* the enactment of the Durham-Humphrey Act. See 17 Fed. Reg. 6818 (1952) codified at 21 C.F.R. §201.105. Therefore, Congress did not, through the Durham-Humphrey Amendment, approve a regulatory "lay use" definition as applied to animal drugs since the Durham-Humphrey Amendment was adopted before the definition was adopted and the Durham-Humphrey Amendment related only to human drugs.

If Congress had concluded that certain essential animal drugs might be characterized as so unsafe that proper labeling with the adequate directions for use could not be devised for them, as concerned the Court of Appeals, it would have said so, in "simple and unambiguous language." *Toilet Goods, supra.*

§502(f) says absolutely nothing about there being some drugs for which no adequate directions can be written for lay use. It simply says that adequate directions for use *shall* be written for all drugs.

The Court of Appeals has in effect pre-empted the right of the petitioner to (1) challenge the need or the reason for any of the animal drugs to bear a "prescription legend" and (2) to establish in the Trial Court, that the labels on said drugs bear "adequate directions for use" under §502(f) so as not to be misbranded.

3. The Decision in This Case Conflicts With Decisions of This Court and Other Courts of Appeals on the Final Judgment Rule.

An order modifying or dissolving a stipulated order between the parties, which provides that it was to remain in effect only "until further order of this Court" is interlocutory in nature and therefore is not immediately appealable.[15] There has been no hearing yet on the FDA's request for injunction.

This settled rule reflects a fundamental policy decision that has been made by Congress,[16] and endorsed repeatedly by this Court,[17] that in all but the most exceptional of

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15. 28 U.S.C. §1292(a)(1).

16. Congress has, of course, carved out a limited exception to the final judgment rule in §1292(a)(1) which provides a right of appeal from an interlocutory decision which grants, denies or dissolves injunctions.

17. *Gardner v. Westinghouse Broadcasting*, 437 U.S. 478, 481 (1978) nt. 7. The Court of Appeals obviously misconstrued the record when it found that an "injunction was dissolved or refused on the merits". There was and has been no hearing or ruling on the merits of any injunction request of the FDA. Actually, it was advanced for hearing on the merits by the very order which the FDA appealed. The FDA moved to stay such a hearing.

circumstances the benefits that may be realized in permitting piecemeal review are far outweighed by the costs, delay in concluding litigation on its merits, and the inevitable drain on scarce judicial resources.

One of the major dangers of the present decision is the blind acceptance of the FDA's erroneous characterization of the record to the effect that there was a denial of its motion for injunctive relief when in fact no hearing on the merits of the requested injunctive relief has even yet occurred and the FDA has filed a motion to stay such hearing.

The Court of Appeals concluded that the order vacating the stipulated order amounted to the dissolution or refusal of an injunction within the meaning of §1292(a)(1). The major vice of the decision was the length to which the Court went to distort the District Court's order by construing the stipulated order as an "injunction" that "was dissolved or refused on the merits" by the Court's order. The District Court's opinion clearly indicated otherwise.

4. The Decision of the Court of Appeals in Effect Granted the FDA's Motion for Preliminary and Permanent Injunctive Relief Without Affording Petitioners a Hearing on the Merits.

Without affording the petitioners with an opportunity to be heard on the merits of the requested preliminary or permanent injunctive relief, the Court of Appeals' decision has preempted the District Court's opportunity to proceed with such a hearing by foreclosing evidence that said drugs are not dangerous or that the prescription legends are not necessary or that adequate directions for use can be demonstrated despite the presence of said cautionary legend. What the Court of Appeals has done is to automatically grant the FDA an injunction based on

a stipulated order agreed to by the parties that was specifically subject to being dissolved by "further order" of the District Court. Such an approach conflicts with due process, the burden of proof for injunctive relief, and contravenes the basic philosophy of determining the justification for the issuance of the extraordinary injunctive relief. The mere presence of a cautionary legend on drugs, without more, should not automatically justify the issuance of the equivalent of a permanent injunction.

CONCLUSION

For these reasons, a Writ of Certiorari should issue to review the judgment and opinion of the Court of Appeals for the Sixth Circuit.

Respectfully submitted,

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May 29, 1981

APPENDIX

MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT

(Filed October 9, 1979)

No. C 78-1470 A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA,
Plaintiff

v.

JERRY J. COLAHAN, *et al.*,
Defendants

MEMORANDUM OPINION AND ORDER

LAMBROS, *District Judge*

This action was brought by the United States under the Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.* ("the Act"), to enjoin defendants (individual distributors of veterinary drugs) from selling certain prescription veterinary drugs directly to dairymen and other customers. A Temporary Restraining Order and a stipulated order were issued, based on the presumed validity of a federal regulation, 21 C.F.R. §201.105. That regulation was promulgated by the Secretary of the then Department of Health, Education and Welfare under the cited statutory authority of 21 U.S.C. §352(f). The question now before the Court is whether §201.105 is a valid and enforceable regulation. It

is agreed that the Act prohibits the introduction or delivery of adulterated or misbranded foods, drugs, devices or cosmetics into interstate commerce, and the

> "adulteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

21 U.S.C. §§331(a), (k). The federal regulation, 21 C.F.R. §201.105, was issued by the Secretary under the authority of 21 U.S.C. §352(f), which provides the following:

> A drug or device shall be deemed to be misbranded—
>
> * * *
>
> (f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in the pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *PROVIDED, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.* (emphasis supplied).

Finally, the controversial regulation, §201.105, reads in part as follows:

> A drug intended for veterinary use which, because of toxicity or other harmful potentiality for harmful effect, or the method of its use, is not safe for animal

> use except under the supervision of a licensed veterinarian, and hence, for which "adequate directions for use" cannot be prepared, shall be exempt from [21 U.S.C. §352(f)(1)] if all the following conditions are met: (a) The drug is . . . sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice. . . . (b) The label of the drug bears: (1) the statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; and (2) The recommended or usual dosage; and (3) The route of administration, if it is not for oral use; and (4) The quantity or proportion of each active ingredient . . . . (c)(1) Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contra-indications and precautions under which veterinarians . . . can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. . . .

The above-emphasized statutory proviso allows the Secretary to act only when the condition stated in §352(f) exists: adequate directions for use as part of the label and packaging contents are unnecessary for protection of the public health. The Secretary may not act when that condition is not evident. If adequate directions for use *are* necessary for the protection of the public health, §352(f) does not provide the Secretary with authority to draft and adopt regulations. Additionally, even when that condition is met, the Secretary is only empowered to make *exemptions* from regulation, not enact more stringent restrictions such as §201.105. However, it is clearly the Secretary's position that adequate directions for use *are* necessary

here to protect the public health, as evidenced by the requirement of a prescription and the cautionary legend. The statute just does not provide regulatory authority for situations such as this where it is claimed that "adequate directions for use" can never be written for the protection of the general public because the drug and its side-effects are so complex that it can be dispensed properly only on the advice of a veterinarian. Thus the Secretary has over the years adopted the position that §352(f) gives him the inherent authority to fill the hiatus in that statute—*i.e.*, the area where certain drugs are necessary for the public health but will always be technically misbranded because "adequate directions for use" are impossible to devise—by enacting regulations such as §201.105. But such administrative action, albeit logical, does not justify judicial addition to the language of the statute because this Court should not be required "to supply an omission in the statute or to hold that Congress must have intended to do that which it has failed to do." *United States v. Goldenberg*, 168 U.S. 95, 103 (1897).

In *United States v. Sullivan*, 332 U.S. 689 (1948), a retail druggist took several pills from a container properly labeled for human drugs and placed them in another container which was not properly labeled. The druggist then sold the pills in the new container. The Supreme Court, in a decision delivered by Justice Black, held that the acts of the druggist violated the requirements of "adequate directions for use." In so holding, the Supreme Court gave a literal construction to the Act. The pharmacist argued in opposition that such a strict ruling would apply to similar sales of foods, drugs and cosmetics. The majority noted that that conclusion would not necessarily follow, and that statement was further explained in the concurring opinion of Justice Rutledge. In his analysis, Justice Rutledge dis-

cussed the proviso to §352(f), which of course concerns the Court today:

> . . . The intent to protect the public health is further emphasized with the limited scope of the proviso, which directs the [Secretary] to make exemptions only when compliance with clause (1) "is not necessary for the protection of the public health." . . . Under [§352(f), the Secretary] is given no power to exempt on the ground that compliance is impracticable. He cannot weigh business convenience against protecting the public health. Only where he finds that labeling is not necessary to that protection is he authorized to create an exemption for drugs and devices. Health security is not only the first, it is the exclusive, criterion.

332 U.S. at 702-703. It is thus clear to this Court that a common sense, literal reading of §352(f) is called for, although the Court is aware that such a position may come as a shock to the FDA at this late date, especially since other courts have long since allowed the Secretary the wide latitude and discretion claimed here. *See, e.g., United States v. El-O-Pathic Pharmacy,* 192 F.2d 62 (9th Cir. 1951).

Although administrative regulations are entitled to a presumption of validity, they can be annulled and found unenforceable when in excess of statutory authority as determined by the natural and plain meaning of the Congressional enactment. *See, e.g. Osaka Shosen Kaiska Line v. United States,* 300 U.S. 98, 101 (1937); *Western Union Tel. Co. v. F.C.C.,* 541 F.2d 346 (3rd Cir.), *cert. denied,* 429 U.S. 1092 (1976); *Diamond Roofing Co. v. O.S.H.R.C.,* 528 F.2d 645 (5th Cir. 1976). Despite the equities of this case and the Secretary's admirable concern for the health of all citizens, the Court feels it is bound by that principle to

reach the result found here. Finally, the Court does not view this case as one where the agency's historical interpretation of one of its enabling statutes is to be afforded considerable deference. *See, e.g., Young v. Tennesseee Valley Authority,* ..... F.2d ....., No. 77-1243 (6th Cir., Sept. 24, 1979). At least at this juncture, it is not clear that Congress has explicitly ratified the agency's interpretation as in *Young.* But most importantly, the statute in question in *Young* was arguably ambiguous on its face, whereas here the proviso to §352(f) speaks plainly and unequivocally. *See* discussion *infra.*

From the beginning of this action, the Government has relied upon §352(f) as the statutory authorization for §201.105. However, the Government has since modified its position to assert additional statutory authority under 21 U.S.C. §260b(d)(1), the New Animal Drug Amendment, as well as 21 U.S.C. §371(a). To begin with, §360b was not enacted until 1968, whereas the key language of §201.105 was promulgated years earlier. Therefore, §360b cannot have been the statutory basis for §201.105. Whether the Secretary could in the future require a prescription and cautionary legend under §360b in an entirely different issue than the one presently before the Court; application of §360b to the facts here is still an undetermined question, and further consideration may well result in an alternative basis for liability. The primary question at this time is still whether the §201.105 stood upon firm statutory footing when promulgated.

Section, §371(a) provides as follows:

> This authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

The authority of the Secretary to make binding regulations under §371(a) is not challenged. Surely, such a challenge

would be fruitless, as demonstrated by the Second Circuit in *National Nutritional Foods Association v. Weinberger*, 512 F.2d 688, 696-697 (2nd Cir.), *cert. denied*, 423 U.S. 323 (1975):

> Whatever doubts might have been entertained regarding the FDA's power under [§371(a)] to promulgate binding regulations were dispelled by the Supreme Court's recent decision in *Weinberger v. Hyson, Westcott & Dunning, nc.*, 412 U.S. 609, 93 S. Ct. 2469, 37 L.Ed. 2d 207 (1973), and its campanion cases, *Ciba Corp. v. Weinberger*, 412 U.S. 640, 93 S. Ct. 2495, 37 L.Ed. 2d 230 (1973); *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 93 S.Ct. 2488, 37 L.Ed. 2d 235 (1973); *U.S.V. Pharmaceutical Corp. v. Weinberger*, 412 U.S. 655, 93 S.Ct. 2498, 37 L.Ed. 2d 244 (1973). Those decisions interpreted [§371(a)] as giving FDA the power to promulgate substantive regulations having the binding force of law rather than mere "interpretative" standards enforceable only on a case-by-case basis through plenary suits against those refusing to comply.

However, what is challenged here is whether §201.105 was properly promulgated in the first place, and hence entitled to the binding effect afforded by §371(a). The Government asserts that FDA interpretations of §371(a) and the regulation cloaks §201.105 with an authoritive blanket. However, the rule that agency construction of its own regulations is entitled to great weight only applies where the relevant statutory language is unclear or susceptible to differing interpretations. *See Young v. Tennessee Valley Authority, supra; Air Transport authority Association of America v. Brownell*, 124 F.Supp. 909 (D.D.C. 1954). Thus, where the language of a statute is clear on its face, a court cannont avoid its duty of so construing the statute by

deferring to a prior, contrary agency interpretation. *Aviation Consumer Action Project v. C.A.B.*, 412 F.Supp. 1028 (D.C. 1976), *motion granted in part, denied in part*, 418 F.Supp. 634 (1976). Furthermore, agency decisions which rest on an erroneous legal foundation, or which are inconsistent with a statutory mandate, should be struck down, *N.L.R.B. v. Brown*, 380 U.S. 278, 291-292 (1965), and are not persuasive in judicial proceedings. *Florida Citus Exchange v. Folsom*, 246 F.2d 850 (5th Cir. 1957), *reversed on other grounds*, 358 U.S. 153, *reh. denied*, 358 U.S. 948 (1958).

The Government asserts that the Secretary relied on §371(a) in enacting §1.106, now §201.105, as evidenced by Exhibit A attached to its Third Memorandum. Section 371(a) is a general grant of authority to enact regulations for the limited purpose of efficient enforcement of the Act. Accordingly, a regulation exempting veterinary drugs from providing adequate directions for use must necessarily be consistent with the Congressional mandate of §352(f) that exemptions from such regulation be limited to the circumstances stated therein. Thus the regulation, being in excess of the narrow authority granted by §352(f), could not properly be found valid under the general grant of authority in §371(a). The regulation could not have been promulgated for the "efficient enforcement" of the Act when the Act specifically limits such regulation in §352(f). As with the direct analysis under §352(f), the Secretary has also gone beyond the broader, but still limited grant of authority of §371(a). It is not the function of the courts to vindicate the wisdom of the law, *Merchants' Insurance Company v. Ritchie*, 5 Wall 541, 18 L.Ed. 540, 544, 545 (1867), but rather it is the duty of the Court to interpret a statute as it finds it, without reference to whether its provisions are wise or unwise. *United States*

v. South-Eastern Underwriters Association, 322 U.S. 533, 561 (1943); *Olsen v. Nebraska*, 313 U.S. 236, 247 (1940). Finally, the Secretary has amended the complaint to allege (1) adulteration of drugs and (2) improper application for permission to sell new animal drugs under 21 U.S.C. §360b. While the government legitimately may be able to proceed against the defendants for the relief it seeks under those amendments, the Temporary Restraining Order and the stipulated order were not entered on the basis of either of those legal theories. Hence the Court chooses not to address them.

In light of the above discussion the Court finds that there is considerable doubt at this stage whether plaintiff would prevail on the merits, and thus the Temporary Restraining Order and the accompanying stipulated order must be vacated. Rule 65(b), Fed. R. Civ.P. That is not to say, however, that further proceedings will not vindicate the Secretary's position and ultimately entitle plaintiff to the relief sought. Accordingly, the Court cautions against incorrect interpretation of this order. The Court does not hold that the Secretary cannot protect the public health. The Court does not hold that defendants did not violate the Act and that defendants cannot at some point be prevented from selling dangerous drugs which humans may indirectly consume. Those issues have yet to be decided. Rather, the Court holds only that these defendants canont be enjoined at this time from the conduct complained of under the authority of §201.105.

A pretrial conference with the Court is scheduled for November 15, 1979 at 1:30 p.m.

IT IS SO ORDERED.

/s/ THOMAS D. LAMBROS
United States District Judge

ORDER OF THE UNITED STATES DISTRICT COURT

(Filed February 12, 1980)

No. C 78-1470 A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA,
Plaintiff

v.

JERRY J. COLOHAN [sic], *et al.*,
Defendants

ORDER

LAMBROS, *District Judge*

In November, 1978, the United States brought this action under the Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, to enjoin defendants (several distributors of veterinary drugs) from selling nine prescription veterinary drugs directly to dairymen and other customers ("Cleveland case"). The Cleveland defendants are: Jerry J. Colohan [sic], an individual doing business as IBA of Ohio, and Norman F. Bauer, Robert L. Berkshire, John D. Burrows, Russell C. Humphrey, Jr., Simon E. Miller and Ralph A. Scharver. A temporary restraining order and a stipulated order were issued, based on the presumed validity of a federal regulation, 21 C.F.R. §201.105. In October of 1979, this Court questioned the validity of §201.105 and whether it was clothed with a statutory authoritative

blanket. The Court ordered the temporary restraining order and the stipulated order be vacated because there was considerable doubt at that time whether plaintiff would prevail on the merits, Rule 65(b), Fed. R. Civ. P., in light of the clear meaning of 21 U.S.C. §352(f) and the analysis of Justice Rutledge in a concurring opinion in *United States v. Sullivan*, 332 U.S. 689 (1948). The Court continued to caution against incorrect interpretation of the October order:

> The Court does not hold that the Secretary cannot protect the public health. The Court does not hold that defendants did not violate the Act and that defendants cannot at some point be prevented from selling dangerous drugs which humans may indirectly consume. Those issues have yet to be decided. Rather, the Court holds only that these defendants cannot be enjoined at this time from the conduct complained of under the authority of §201.105.

Almost a year after the filing of the Cleveland case but before the October, 1979 order, the United States filed an action in the United States District Court in the District of Massachusetts, Case No. CA 79-1643-F, ("Massachusetts case"), against IBA, Inc., a Massachusetts corporation, and Daniel J. Belsito, the president of the corporation. IBA, Inc. is the franchisor of the defendant franchisees in the Cleveland case. The Massachusetts case also was brought on the presumed validity of the same federal regulation, §201.105, in the Cleveland case.

The holding in the Cleveland case that the temporary restraining order is vacated allows the defendant franchisees to continue to sell the drugs at this time. Conceivably, the court in the Massachusetts case could grant the government's motion for a preliminary injunction by ruling that §201.105 appears to be a validly promulgated regula-

tion. The effect of such a ruling would prevent IBA, Inc. from distributing the drugs to the Cleveland defendants; the ruling could cut off the source of the Cleveland defendants' products. Such a situation would create a dilemma by the duplicative litigation. Additionally, both cases involve similar questions of law and fact.

Rule 19(a), Fed. R. Civ. P. provides:

> A person who is subject to service of process and whose joinder will not deprive the court of jurisdiction over the subject matter of the action shall be joined as a party in the action if (1) in his absence complete relief cannot be accorded among those already parties, or (2) the claims an interest relating to the subject of the action is so situated that the disposition of the action in his absence may (i) as a practical matter impair or impede his ability to protect that interest or (ii) leave any of the persons already parties subject to a substantial risk of incurring doubles, multiple, or otherwise inconsistent obligations by reason of his claimed interest. If he has not been so joined, the court shall order that he be made a party. . . . If the joined party objects to venue and his joinder would render the venue of the action improper, he shall be dismissed from the action.

It is obvious from the circumstances caused by the United States in filing the two actions and the relationship between the Massachusetts defendants and the Cleveland defendants that complete relief cannot be accorded to the Cleveland defendants; the Massachusetts defendants have an interest in the Cleveland case to the extent that any determination in the Cleveland case would impair their ability to protect that interest as well as subject the Cleveland defendants to substantial risk of incurring inconsistent obligations. Additionally, venue is proper in Cleveland

as evidenced by admissions of IBA, Inc. doing business within the jurisdiction of this Court as well as the franchisor-franchisee relationship between the defendants in both cases. Accordingly, IBA, Inc. and Daniel J. Belsito are hereby joined as party defendants in the Cleveland case.

Plaintiff has moved for a reconsideration of the October, 1979 order. The Court finds no meritorious basis to reconsider the order and position of this Court. A substantial question remains as to whether the regulation, §201.105, exceeds the statutory grant of authority of §352 (f), notwithstanding the agency's good intentions. Accordingly, plaintiff's motion for reconsideration of the October, 1979 order is denied.

Plaintiff has moved for certification of an interlocutory appeal, 28 U.S.C. §1292(b). Upon consideration, the Court finds that the time for such an appeal is not ripe because the Court has not issued a final order on the issue of the validity of §201.105. Thus, plaintiff's motion is denied. Plaintiff's motion for a stay pending appeal, therefore, is moot. This case shall proceed to trial on the merits.

IT IS SO ORDERED.

/s/ THOMAS D. LAMBROS
United States District Judge

OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

(Filed December 11, 1980)

No. 79-3767

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

UNITED STATES OF AMERICA,
Plaintiff-Appellant,

v.

JERRY J. COLAHAN, *et al.*,
Defendants-Appellees.

APPEAL from the United States District Court for the Northern District of Ohio, Eastern Division.

Before MERRITT and BROWN, *Circuit Judges;* GUY, *District Judge.**

BAILEY BROWN, *J.* The government brought this action against Colahan and others (herein collectively referred to as Colahan), alleging that Colahan sold veterinary drugs directly to dairy farmers without a prescription in violation of an applicable regulation promulgated by the Food and Drug Administration (FDA). The district court issued a temporary restraining order. This was replaced six days later by a stipulated order in which Colahan agreed not to distribute nine veterinary drugs until further order of the court. Colahan moved the court after about two

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*Honorable Ralph B. Guy, Jr., United States District Judge for the Eastern District of Michigan, sitting by designation.

months to vacate the stipulated order on the ground that FDA did not have authority to require a prescription in connection with the sale of these drugs. Almost a year later, the district court, recognizing that the question before it was whether the FDA had authority to promulgate the regulation upon which it relied and concluding that FDA did not have such authority, granted the motion to vacate. The district court denied the government's motion to reconsider, denied a certification under 28 U.S.C. § 1292b, and denied a stay pending appeal. The government now appeals.

The government's appeal raises two issues. First, whether the court's action in granting the motion to vacate the stipulated order prohibiting the dispensing of the drugs except by veterinarian's prescription is appealable. Second, if the order is appealable, whether the court's ruling was in error and requires reversal by this court.

The government contends that the district court's ruling is appealable under 28 U.S.C. § 1292(a)(1).[1] This section provides a right of appeal from interlocutory decisions which grant, deny, or dissolve injunctions. The record here shows that the order from which the government appeals dissolved, over the government's objection, the stipulated order which prohibited distribution of drugs except by prescription.

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1. § 1292. Interlocutory decisions

(a) The courts of appeals shall have jurisdiction of appeals from:

(1) Interlocutory orders of the district courts of the United States, the United States District Court for the District of the Canal Zone, the District Court of Guam and the District Court of the Virgin Islands, or of the judges thereof, granting, continuing, modifying, refusing or dissolving injunctions, or refusing to dissolve or modify injunctions, except where a direct review may be had in the Supreme Court; . . . .

We conclude that the order vacating the stipulated order amounted to the dissolution or refusal of an injunction within the meaning of § 1292(a)(1). The basis for the district court's vacating of the order was its opinion that the FDA had no authority, as a proposition of law, to require that the drugs be distributed only pursuant to a prescription. Thus the injunction was dissolved or refused on the merits. *Gardner v. Westinghouse Broadcasting Co.*, 437 U.S. 478, 481, n. 7 (1978).

As we find the order is appealable, we must consider whether it was an error to vacate the order enjoining Colahan from distributing the nine veterinary drugs. While a district court's refusing or dissolving of a temporary injunction can be reversed on appeal only if it is determined that the district court abused its discretion, if the district court erred as a matter of law, as the government here contends, such would be an abuse of discretion. *United States v. Beaty*, 288 F.2d 653 (6th Cir. 1961).

FDA contends that, in selling the involved drugs to dairy farmers, the drugs thereby become "misbranded" within the meaning of 21 U.S.C. § 352(f) which provides:

> A drug or device shall be deemed to be misbranded—
>
> . . . .
>
> (f) Unless its labeling bears (1) adequate directions for use . . . . *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

In this connection, FDA relies on 21 C.F.R. § 201.5 which provides in part:

> "Adequate directions for use" means directions under which the layman can use a drug safely and for the purposes for which it is intended.

The FDA further relies on 21 C.F.R. § 201.105 which provides in part:

> A drug intended for veterinary use which, because of toxicity or other potentiality for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section §502(f)(1) of the Act if all the following conditions are met:
>
> (a) The drug is:
>
> (1) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of veterinary drugs and is to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice; or
>
> (2) In the possession of a licensed veterinarian for use in the course of his professional practice.
>
> (b) The label of the drug bears:
>
> (1) The statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" . . . .
>
> (c)(1) Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contrain-

> dications, side effects, and precautions under which veterinarians licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented . . . .

FDA contends that directions cannot be written which would permit a layperson to use these drugs safely. Therefore, under 21 U.S.C. § 352(f), "adequate directions for use" cannot be written. Thus, contends FDA, under the proviso contained in § 352(f), it may require by regulation, as it has, that such drugs are exempt and thus approved for distribution *only* if the requirements of 21 C.F.R. § 201.105 are met since professional direction, in the words of the statute, "is necessary for the protection of the public health."

Colahan contends, and the district court ruled, that FDA had no authority to issue the regulation 21 C.F.R. § 201.105. As stated in the district court's opinion vacating the stipulated order:

> The above-emphasized statutory proviso allows the Secretary to act only when the condition stated in § 352(f) exists: adequate directions for use as part of the label and packaging contents are unnecessary for protection of the public health. The Secretary may not act when that condition is not evident. If adequate directions for use *are* necessary for the protection of the public health, § 352(f) does not provide the Secretary with authority to draft and adopt regulations. Additionally, even when that condition is met, the Secretary is only empowered to make *exemptions* from regulation, not enact more stringent restrictions such as § 201.105. However, it is clearly the Secretary's position that adequate directions for use *are* necessary here to protect the public health, as evi-

denced by the requirement of a prescription and the cautionary legend. The statute just does not provide regulatory authority for situations such as this where it is claimed that "adequate directions for use" can never be written for the protection of the general public because the drug and its side-effects are so complex that it can be dispensed properly only on the advice of a veterinarian.

We conclude that, while the language of 21 U.S.C. § 352(f) and particularly the proviso therein would suggest that the FDA could exempt a drug only when directions for use are not needed, the proviso is also subject to the interpretation argued by the government. We further conclude that the government's interpretation is the correct one. We therefore reverse the decision of the district court. The reasons for our conclusion are as follows:

First, Colahan's interpretation of the statute reaches a totally unreasonable result. His interpretation would require that the FDA either allow unrestricted over-the-counter sale of all veterinary drugs or withdraw useful drugs from the market that the FDA considers to be dangerous unless sold by prescription.

We are also persuaded by the FDA's longstanding exercise of authority to issue and enforce this regulation. FDA first promulgated the challenged regulation in 1938. This administrative interpretation over many years is entitled to great weight. *Commissioner v. First Security Bank*, 405 U.S. 394, 403, n. 16 (1972). Implementation of the Act's complex statutory scheme is a job entrusted in the first instance to the FDA. Therefore, since there is more than one reasonable interpretation of this statute, the court should follow the interpretation urged by the

FDA. *Udall v. Tallman*, 380 U.S. 1 (1965); *United States v. Articles of Drug*, ... F.2d ..... (5th Cir. 1980).

Further supporting FDA's position is the clear indication that Congress has been aware since 1938 of the FDA's interpretation of its statutory authority while it was legislating in this area, and yet Congress has not restricted such FDA authority. Congress passed the Durham-Humphrey Amendments in 1951. 65 Stat. 648 (1951). This amended parts of the Act's regulatory scheme. The House report noted awareness of the authority asserted by the FDA. In discussing "adequate directions for use," the report stated:

> Drugs suitable for use only by or under the direction of a licensed practitioner have been exempted from the adequate directions requirement on condition that they be labeled . . . [with the prescription legend]. H.R. Rep. No. 700, 82d Cong., 1st Sess. 4 (1951).

Despite Congressional awareness of the FDA's interpretation of its authority under the Act, and despite revisions of the Act in 1951 and 1962,[2] Congress has not eliminated or modified FDA's asserted authority. "[A]n agency's longstanding construction of its statutory mandate is entitled to great respect, 'especially when Congress has refused to alter the administrative construction.'" *Board of Governors v. First Lincolnwood Corp.*, 439 U.S. 234, 248 (1978). Once an agency's interpretation of a statute has been brought to the attention of Congress, and Congress has not sought to alter that interpretation although it has amended the statute in other respects, then presum-

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2. See Drug Amendments of 1962, Pub.L.No. 87-781, 76 Stat. 780 (1962); Federal Food, Drug, and Cosmetic Act Amendments (Durham-Humphrey amendments) Pub.L.No. 82-215, 65 Stat. 648 (1951).

ably the legislative intent has been correctly discerned. *United States v. Rutherford,* 442 U.S. 544, 554, n. 10 (1979).

Lastly, this assertion of FDA authority has been recognized and approved by the courts. *United States v. El-O-Pathic Pharmacy,* 192 F.2d 62 (9th Cir. 1951); *United States v. Articles of Drug,* ..... F.2d ..... (5th Cir. 1980).

Therefore, we conclude that the district court erred as a matter of law in dissolving the stipulated order preventing Colahan from dispensing certain veterinary drugs without prescription on the ground that FDA had no authority to require prescriptions as a prerequisite to dispensing of the drugs. We remand with instructions to the district court to reinstate the stipulated order and for further proceedings not inconsistent with this opinion.

ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT DENYING MOTION FOR REHEARING

(Filed March 5, 1981)

No. 79-3767

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

v.

JERRY J. COLAHAN,
Defendant-Appellant.

ORDER

Before: MERRITT and BROWN, *Circuit Judges;* GUY, *District Judge.**

On receipt and consideration of a petition for rehearing and suggestion for rehearing en banc in the above styled case; and

No judge in active service in this court having moved for rehearing en banc and the motion therefore having been referred to the panel which heard the case; and

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*The Honorable Ralph B. Guy, Jr., United District Judge for the Eastern District of Michigan, sitting by designation.

The panel having noted nothing of substance in said motion for rehearing which had not been carefully considered before issuance of the court's opinion;

Now, therefore, it is Ordered that the motion for rehearing be and the same is hereby denied.

ENTERED BY ORDER OF THE COURT

/s/ JOHN P. HEHMAN
Clerk

Office-Supreme Court, U.S.
FILED
AUG 4 1981
ALEXANDER L. STEVAS,
CLERK

No. 80-2067

In the Supreme Court of the United States

OCTOBER TERM, 1980

JERRY J. COLAHAN, ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the Food and Drug Administration reasonably could interpret Section 502(f) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 352(f), as authorizing it to declare some drugs "not safe for animal use except under the supervision of a licensed veterinarian" and to impose restrictions on the labeling, distribution and use of those veterinary drugs.

2. Whether the district court's order vacating a stipulated order which prohibited petitioners from dispensing certain veterinary drugs had the effect of dissolving a preliminary injunction and therefore was appealable under 28 U.S.C. 1292(a)(1).

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In the Supreme Court of the United States

OCTOBER TERM, 1980

No. 80-2067

JERRY J. COLAHAN, ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A14-A21) is reported at 635 F.2d 564. The memorandum opinion and order of the district court filed October 9, 1979 (Pet. App. A1-A9) and the order of the district court filed February 12, 1980 (Pet. App. A10-A13) are unreported.

JURISDICTION

The judgment of the court of appeals was entered on December 11, 1980, and a petition for rehearing was denied on March 5, 1981 (Pet. App. A22-A23). A petition for a writ of certiorari was filed on June 2, 1981.

The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTE AND REGULATIONS INVOLVED

Pertinent portions of Section 502 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 352, and 21 C.F.R. 201.105 are reprinted at Pet. 2-4. In addition, 21 C.F.R. 201.5 provides in pertinent part:

> "Adequate directions for use" means directions under which the layman can use a drug safely and for the purposes for which it is intended.

21 C.F.R. 201.110 provides:

> A drug subject to § 201.105 shall be exempt at the time of delivery to the ultimate purchaser or user from section 502(f)(1) of the act if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

STATEMENT

1. Section 502(f) of the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. 352(f), requires that drugs[1] bear "adequate directions for use," and drugs that fail to do so are deemed to be misbranded. The term "adequate directions for use" means use by laymen. 21 C.F.R. 201.5 A proviso to Section 502(f), however, authorizes the FDA to exempt drugs from this labeling requirement where it "is not necessary for the protection of the public health."

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[1] Section 201(g)(1) of the Act defines "drugs" to include both human and veterinary drugs. 21 U.S.C. 321(g)(1).

Since 1938, the FDA has recognized that some drugs cannot be used safely except under a veterinarian's supervision and these by definition cannot be labeled adequately for laymen's use. Such drugs nonetheless can be of great medical benefit when used under the direction of a licensed health professional. Thus, rather than totally ban the drugs as misbranded, the FDA has exempted them under the Section 502(f) proviso so long as they are sold pursuant to a veterinarian's prescription or other order. The agency's rationale is that "adequate directions for use" are not "necessary" because the veterinarian's directions protect the public health. The result of this policy is that many useful veterinary drugs are now available which otherwise would have to be withdrawn.[2]

The current regulations basically specify three relevant conditions for exemption. The drugs must be distributed by persons who are "regularly and lawfully engaged in" the handling of such drugs. 21 C.F.R. 201.105(a)(1). The drugs must be "sold only to or on the * * * order of" a licensed practitioner for use in his professional practice. *Ibid.* The drugs must bear, *inter alia*, a legend stating: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." 21 C.F.R. 201.105(b)(1).

Veterinary drugs which can be used properly only under the supervision of a veterinarian but which do

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[2] Nearly half of the roughly 1200 veterinary drugs for which the agency has approved New Animal Drug Applications (see Section 512 of the Act, 21 U.S.C. 360b) are labeled for use only by or on the order of a veterinarian. Included are narcotics, barbiturates, anesthetics, anticonvulsants, hormones (including steroids), stimulants and tranquilizers.

not satisfy all three conditions for exemption are misbranded because they do not and cannot bear adequate directions for lay use.

2. On November 3, 1978, the United States filed this action in the United States District Court for the Northern District of Ohio, requesting an injunction against petitioners to stop them from receiving and selling "misbranded" drugs in violation of Section 301 of the Act, 21 U.S.C. 331.[3] The complaint alleged numerous instances in which petitioners, without a prescription or other order, sold drugs that require a veterinarian's directions for safe use.[4] The complaint also alleged that petitioners are not "regularly and lawfully engaged in" the distribution of drugs that are restricted to use under a veterinarian's directions. Since the drugs did not satisfy the conditions for exemption under 21 C.F.R. 201.105, they were misbranded.

On November 3, 1978, the district court issued a temporary restraining order that broadly prohibited petitioners from distributing misbranded drugs. Six days later, the court entered a stipulated order pursuant to which petitioners agreed not to distribute nine named drugs until further order of the court. On November 14, 1978, the court permitted the tem-

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[3] Section 301(a) of the Act, 21 U.S.C. 331(a), prohibits the introduction or delivery for introduction into interstate commerce of any misbranded drug. Section 301(k), 21 U.S.C. 331(k), prohibits the doing of any act to any drug while held for sale after shipment in interstate commerce which results in the article being misbranded.

[4] Steroids and other hormones were among the drugs which petitioners sold. Contrary to their claim (Pet. 9), the record in the trial court did not establish that all or some of the drugs sold by petitioners were available over-the-counter under different names.

porary restraining order to expire, but expressly continued the stipulated order pending a hearing on the government's request for a preliminary injunction. In January 1979, petitioners moved for dissolution or modification of the stipulated order on the ground that the FDA lacked statutory authority to promulgate 21 C.F.R. 201.105.

3. On October 9, 1979, the district court ruled that the FDA lacked authority to promulgate 21 C.F.R. 201.105 (Pet. App. A1-A9). It held that the plain meaning of the proviso to 21 U.S.C. 352(f) exempts only those drugs which are sufficiently safe that directions for use are unnecessary (Pet. App. A3-A4). The court reasoned that Congress never granted the FDA authority to deal with the situation where "adequate directions for use" could not be written (Pet. App. A4). Thus, notwithstanding the longevity or "logic" of the FDA regulation, the court concluded that it was beyond the statutory authority of the FDA to adopt (Pet. App. A8).[5] Accordingly, the court vacated the stipulated order, stating that "these defendants cannot be enjoined at this time" (Pet. App. A9). The government appealed pursuant to 28 U.S.C. 1292(a)(1).

4. The court of appeals reversed (Pet. App. A14-A21). It ruled that "the order vacating the stipulated order amounted to the dissolution or refusal of an injunction within the meaning of § 1292(a)(1)" (Pet. App. A16). On the merits, the court of appeals

[5] The court also rejected the FDA's argument that 21 C.F.R. 201.105 was authorized by Section 701(a), 21 U.S.C. 371(a), which permits the FDA "to promulgate regulations for the efficient enforcement of this Act * * *," and Section 512, 21 U.S.C. 360b, which authorizes restriction of animal drugs to use under veterinary supervision as part of the FDA's premarket approval process (Pet. App. A6-A9).

reasoned that the language of Section 502(f) is susceptible to more than one reasonable construction (Pet. App. A19). The court validated the FDA's interpretation, and concluded that petitioners' interpretation requiring the FDA either to allow the unrestricted sale of dangerous drugs or to forbid all sales of useful drugs was "a totally unreasonable result" (*ibid.*). Moreover, the court of appeals concluded that Congress had been aware of the FDA's longstanding interpretation and that Congress had amended the statute without altering the FDA's construction (Pet. App. A19-A20). Finally, the court of appeals recognized that the FDA's interpretation had been approved previously by two other courts of appeals (Pet. App. A21).

ARGUMENT

The decision of the court of appeals is correct, does not conflict with any decision of this Court or any other court of appeals, and does not merit further review.

1. The court of appeals correctly held that the FDA has statutory authority to promulgate a regulation which exempts veterinary prescription drugs from the "adequate directions for use" requirement of the Act. Section 502(f)(1) declares all drugs to be misbranded unless their label bears "adequate directions for use." 21 U.S.C. 352(f)(1). The FDA, however, is empowered to exempt drugs from this requirement if directions are "not necessary for the protection of the public health." *Ibid.*

Since 1938 the FDA has interpreted this proviso in two ways. First, it has exempted drugs for which "adequate directions * * * are known by the ordinary individual." 3 Fed. Reg. 3168 (1938). Second, it has exempted drugs if, among other requirements, their label bore "the statement 'Caution: To be used

only by or on the prescription of a ————' (the blank to be filled in by the word 'Physician,' 'Dentist', or 'Veterinarian' * * *)." *Ibid.* In the latter situation the exemption from misbranding is justified because the veterinarian provides the directions required to protect the public health. The second interpretation may not be the most obvious one, but it is a reasonable construction of the statutory language, and thus a reviewing court is bound to respect it. See *Udall* v. *Tallman*, 380 U.S. 1, 16-17 (1965).

In addition, the regulation was promulgated contemporaneously with the adoption of the statute and it has remained essentially unaltered for more than 40 years.[6] These are powerful factors supporting its validity. See *United States* v. *Rutherford*, 442 U.S. 544, 553-554 (1979); *Power Reactor Development Co.* v. *International Union of Electrical, Radio & Machine Workers*, 367 U.S. 396, 408 (1961).

Finally, Congress amended the statute long after the regulations had been in effect, but expressly declined to overturn the interpretation adopted by the

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[6] Petitioners' unsupported assertion (Pet. 21) that the FDA did not require directions for "lay use" to apply to "veterinary drugs" until 1952 is simply mistaken. See *Alberty Food Products* v. *United States*, 194 F.2d 463, 464 (9th Cir. 1952); H.R. Rep. No. 700, 82d Cong., 1st Sess. 7 (1951). The 1938 regulations clearly apply to veterinary drugs and refer to "ordinary individuals." 3 Fed. Reg. 3168 (1938).

After Congress amended the Act in 1951 to modify the regulation of human prescription drugs (Act of Oct. 26, 1951, ch. 578, 65 Stat. 648), the FDA revised its regulations exempting drugs that require professional supervision and for many years treated human and animal drugs in the same regulation. 17 Fed. Reg. 6818-6819 (1952) (then codified as 21 C.F.R. 1.106 (1954)). In 1975 the agency recodified the veterinary drug regulations as 21 C.F.R. 201.105. None of these changes, however, altered the basic requirements originally adopted in 1938.

FDA. In 1951 Congress passed the Humphrey-Durham Amendments (Act of Oct. 26, 1951, ch. 578, 65 Stat. 648), to modify the regulation of human prescription drugs. Petitioners make much of the distinction that is drawn in those amendments between the treatment of drugs intended for humans and those for animals (Pet. 11-13). The legislative history, however, shows that Congress recognized the prior interpretation of Section 502(f)(1) relating to animals and approved it.

The clearest explanation of the effect of the amendments on veterinary drugs is in the Senate Report. It states:

> Under the Committee bill, drugs intended for use under the supervision of a veterinarian will not require a prescription, *although it will be possible under section 502(f)* [21 U.S.C. 352(f)] *to exempt such drugs from adequate directions for use if they are to be used by or under the supervision of a veterinarian.*

S. Rep. No. 946, 82d Cong., 1st Sess. 8 (1951) (emphasis added). Thus, Congress was aware of the prior FDA interpretation of 502(f) and chose to alter it, in part, for human drugs,[7] but to leave it

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[7] Contrary to petitioners' assertion (Pet. 12), the purpose of the 1951 Amendments was not to authorize the FDA to require prescription status for human drugs; the agency already had that authority under Section 502(f). Rather they were meant to define by statute the criteria under which human drugs would be deemed prescription or non-prescription. 21 U.S.C. 353(b)(1). S. Rep. No. 946, 82d Cong., 1st Sess. 3-4 (1951); 97 Cong. Rec. 9321, 9325 (1951).

Other purposes of the amendments were to define the term "prescription drug" (21 U.S.C. 353(b)(2)) and to relieve druggists from the risks of prosecution created by this Court's decision in *United States* v. *Sullivan*, 332 U.S. 689 (1948). See page 10, *infra*.

unchanged with regard to veterinary drugs. As one commentator on the Humphrey-Durham Amendments, cited by petitioners, explained:

> The regulations as they now stand and as published in the *Federal Register* of July 25, 1952, are, to all intents and purposes, practically the same with respect to drugs for animal use as they were before. The Act itself has not changed.

Collins, *Federal Drug Regulations as They Apply to Veterinarians*, 8 Food Drug Cosm. L. J. 333, 335 (1953).

Congress did not, as petitioners urge, exempt veterinary drugs from regulation, but instead simply declined to impose the full regulatory regimen of the Humphrey-Durham Amendments on those drugs. It left the prior interpretation of Section 502(f) intact.[8]

Obviously, knowing congressional acquiescence in an agency interpretation of its organic statute attests overwhelmingly to the validity of the agency's regulation. See *Board of Governors* v. *First Lincolnwood Corp.*, 439 U.S. 234, 248 (1978); *Red Lion Broadcasting Co.* v. *FCC*, 395 U.S. 367, 381 (1969). The court of appeals' decision upholding 21 C.F.R. 201.105 as within the FDA's statutory authority is plainly correct.[9]

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[8] Indeed, the exemptions from labeling provided by the amendments in 21 U.S.C. 353(b)(2) apply only from the time of dispensing by the pharmacist. Until then, even human prescription drugs continue to need exemption under the Section 502(f) proviso. *United States* v. *Articles of Drug*, 625 F.2d 665, 672 (5th Cir. 1980).

[9] Congress even more recently acknowledged and approved the FDA's interpretation of Section 502(f). The House Report on the Medical Device Amendments of 1976 states:

> This authority is derived from section 502(f) of the Act, which authorizes exemptions to the requirement

2. The decision of the court of appeals in no way conflicts with this Court's decision in *United States* v. *Sullivan*, 332 U.S. 689 (1948). Indeed, petitioners actually argue (Pet. 20) that the decision conflicts in principle only with the concurring opinion of Justice Rutledge. 332 U.S. at 703. Neither the opinion of the Court nor Justice Rutledge's concurring opinion casts any doubt upon the validity of the court of appeals' decision.

In *Sullivan*, a pharmacist transferred tablets from a properly labeled bottle to another bottle bearing only the name of the drug and then sold the second bottle to consumers. The Court held that the second bottle lacked "adequate directions for use" and held that application of the Act to Sullivan's situation was constitutional. 332 U.S. at 695-698. Obviously, those holdings are irrelevant to this case.

Justice Rutledge, in his concurring opinion, discussed Section 502(f), 21 U.S.C. 352(f), and referred to "the limited scope of the proviso, which directs

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that all devices bear adequate directions for use. The Food and Drug Administration's contention that such an exemption may be conditioned upon the use of a device only by or on the order of a licensed practitioner has been upheld by the courts.

H.R. Rep. No. 853, 94th Cong., 2d Sess. 24-25 (1976).

Petitioners argue (Pet. 13) that recent legislation proposed by the FDA to clarify its authority over veterinary drugs, H.R. 7035, 96th Cong., 2d Sess. (1980), is an indication that the FDA now recognizes its limited authority in this area. That legislation, however, was proposed solely in response to the district court's decision in this case. Prior to that decision, the FDA never doubted its authority to adopt 21 C.F.R. 201.105. The FDA's request for this clarification is no indication that its prior interpretation was incorrect. See *American Trucking Associations* v. *Atchison, T. & S.F. Ry.*, 387 U.S. 397, 418 (1967).

the Administrator to make exemptions only when compliance with clause (1) 'is not necessary for the protection of the public health'." 332 U.S. at 702. The point of this reference, however, was to assure owners of corner grocery stores that misbranding under the decision of the Court did not apply to most classes of foods and thus they need not fear prosecution for mislabeled "candies." *Id.* at 703. Justice Rutledge in no way suggested that the proviso should be afforded a narrow interpretation where, as here, potentially dangerous drugs are involved.

3. The court of appeals' holding is consistent with the only other decisions of courts of appeals that have reviewed the FDA's interpretation of 21 U.S.C. 352(f). In *United States* v. *Articles of Drug*, 625 F.2d 665, 674 (5th Cir. 1980), the court recently held that "the agency's view is that they [prescription drugs] pose no threat to the public health prior to dispensing so long as they comply with the terms of the exemption in the regulation [21 C.F.R. 201.100, the human drug equivalent of 201.105]. This view is certainly a reasonable interpretation of the statute." See also *United States* v. *El-O-Pathic Pharmacy*, 192 F.2d 62 (9th Cir. 1951). This uniformity of appellate court opinion makes review of this issue by this Court unnecessary.[10]

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[10] Petitioners also argue (Pet. 21) that the court of appeals wrongly decided "an issue which the District Court has not yet reached * * * whether by the mere affixation [by a manufacturer, presumably] to a label of an animal drug of a warning 'Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian,' it is *per se* impossible for 'adequate directions for use' to be written as required by § 502(f)." The court of appeals decided no such thing. The court, of course, upheld 21 C.F.R. 201.105, but that regulation requires a cautionary legend only if adequate directions for

4. Petitioners' second contention, that the court of appeals erred in allowing an appeal from the district court's order under 28 U.S.C. 1292(a)(1), is equally unworthy of review by this Court. The court of appeals correctly held that the district court's October 9, 1979, order had the effect of dissolving a preliminary injunction (Pet. App. A16). The district court dissolved a stipulated order which in turn had replaced a temporary restraining order.

This Court has recognized that a temporary restraining order that is extended beyond the 20-day limit in Fed. R. Civ. P. 65(b) can be treated for purposes of appeal as a preliminary injunction. See *Sampson* v. *Murray*, 415 U.S. 61, 86-87 (1974). Thus, the stipulated order should be treated as a preliminary injunction in this case. The district court's decision on the merits and over the United States' objection to dissolve the stipulated order created a right to immediate appeal. See *Gardner* v. *Westinghouse Broadcasting Co.*, 437 U.S. 478, 481 n.7 (1978).

Alternatively, the October 9, 1979, order could be viewed as a denial of the government's motion for a preliminary injunction (Pet. App. A16). The district court held that the government was unlikely to prevail on the merits and expressly stated that petitioners "cannot be enjoined at this time from the conduct complained of under the authority of § 201.105" (Pet. App. A9). This is a familiar ex-

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lay use cannot be written. It does not provide that the "mere affixation" of a cautionary legend means that adequate directions for lay use cannot be written. Indeed, where such directions are feasible, a manufacturer's voluntary use of the legend causes the drug to be misbranded under Section 502(a), 21 U.S.C. 352(a).

ercise of equity practice even if the precise words "preliminary injunction" were not used. Cf. *Ettelson* v. *Metropolitan Life Ins. Co.*, 317 U.S. 188, 192 (1942).[11] Therefore, an immediate appeal was appropriate.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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[11] The court of appeals' reversal and remand do no more than direct the district court to reinstate the stipulated order which it dissolved because of its erroneous view of the lawfulness of 21 C.F.R. 201.105. Contrary to petitioners' contention (Pet. 23-24) the court of appeals has neither permanently enjoined their distribution of the nine disputed drugs nor has it prevented petitioners from demonstrating that these drugs can be adequately labeled for lay use. In fact, the court directed the lower court to conduct further proceedings (Pet. App. A21).

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